

REMARKS

I. Status of the Claims

Claims 1-57 are pending in the application and stand rejected, variously, under 35 U.S.C. §112, second paragraph, 35 U.S.C. §102 and 35 U.S.C. §103. The specific grounds for rejection are set forth in detail below.

Claims 1, 24, 30, 32, 33, 37, 39, 55 and 57 are amended herein. Claims 23, 51-54 and 56 are canceled. Thus, claims 1-22, 24-50, 55 and 57 are presented for reconsideration. Support the amendments can be found throughout the specification and claims as filed.

II. Rejections Under 35 U.S.C. §112, Second Paragraph

Claims 1-57 stand rejected as allegedly indefinite. First, the examiner questions whether the “%” of carbon particles used in the claims refers to percent by weight or volume. As discussed at page 32 and 45, carbon black was obtained as a *suspension* at 6% from Sanford Corp. By definition, suspensions are defined as weight % and not volume. Second, the examiner questions whether the diameter of the carbon particles is mean or absolute, and whether the diameter is before or after suspension. Page 32 describes the heterogeneous size of carbon particles, and thus the diameter stated clearly is mean, and not absolute. And again, since applicants obtained carbon black as a *suspension*, the diameters provided are after suspension. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

III. Rejections Under 35 U.S.C. §102

A. *Lucci et al.*

Claims 1-25, 30-35, 37-46, 48-54 and 56 stand rejected under §102(a) over *Lucci et al.*

Applicant respectfully traverses.

Claim 1 has been amended to recite the elements of previous claims 24 and 51-54:

1. (Presently amended) A method of identifying a disease-associated sentinel lymph node in an excised tissue sample, comprising,
 - a) administering administering to a subject (i) at least one fluid composition comprising of from about 0.1% carbon particles to about 6.0% carbon particles and (ii) and a standard sentinel lymph node identifier[[,]];
 - b) excising at least one tissue sample suspected of comprising at least one a sentinel lymph node[[,]];
 - c) identifying a sentinel lymph node by a combination of the accumulation of said carbon particles and the standard sentinel lymph node identifier[[,]] and[[;]]
 - d) identifying, diagnosing, staging or predicting the presence of neoplastic tissue in said lymph node based on histopathology of a subregion of the sentinel lymph node identified by carbon particle accumulation.

In contrast to the examiner's assertion, *Lucci et al.* does **not** disclose each of these elements.

Lucci et al. merely describes the use of carbon particles and a dye to identify, for surgical resection, tumor draining lymph nodes. The present claims provide a far more sophisticated analysis that goes beyond the gross surgical technique described by *Lucci et al.* Instead, the present claims provide use of carbon particles not only as confirmation that the sentinel lymph node has been identified, by they permit the subsequent determination of a particular **sub**-region of the lymph node for evaluation. A complete histological analysis of every excised node is impractical (if not impossible), and the present inventor has discovered that carbon particles deposit in those regions of lymph nodes most likely to contain metastatic cells. Thus, step (d) of

claim 1 now provides for a very unique and specific application, which is nowhere disclosed in *Lucci et al.*

Thus, in light of the foregoing, applicant submits that *Lucci et al.* does not disclose the invention as presently claimed. Reconsideration and withdrawal of the rejection is therefore respectfully requested.

Furthermore, applicants are currently preparing a “Katz” declaration that will demonstrate that *Lucci et al.* is not “by another,” and hence not properly cited as prior art under §102.

B. Kitamura et al.

Claims 1-16, 22, 23, 40, 41, 44, 45 and 47-55 stand rejected under §102(b) as anticipated by *Kitamura et al.* Applicant respectfully traverses.

As discussed above, claim 1 has been amended to recite the elements of claim 24. As claim 24 was not rejected over *Kitamura et al.*, it is believed that claim 1 is novel over the reference. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

IV. Rejections Under 35 U.S.C. §103

A. Lucci et al.

Claims 1-57 stand rejected under §103(a) as obvious over *Lucci et al.* Applicant respectfully traverses. As discussed above, *Lucci et al.* fails to describe the specific aspects of claim 1, step (d), as now presented for reconsideration. The absence of this element from the reference precludes the finding of a *prima facie* case of obviousness. *In re Vaeck*, 20 USPQ2d

1438 (Fed. Cir. 1991). Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

Furthermore, applicants are currently preparing a “Katz” declaration that will demonstrate that Lucci *et al.* is not “by another,” and hence not properly cited as prior art under §102.

B. Kitamura et al.

Claims 17-21 stand rejected under §103(a) as obvious over Kitamura *et al.* Applicants traverse. As discussed above, claim 1 has been amended to recite the elements of claim 24, which is not rejected over Kitamura *et al.* Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

C. U.S. Patent 6,205,352 and Kitamura et al.

Claims 1-22 stand rejected under §103(a) as obvious over U.S. Patent 6,205,352 and Kitamura *et al.* Applicants traverse. As discussed above, claim 1 has been amended to recite the elements of claim 24, which is not rejected over U.S. Patent 6,205,352 and Kitamura *et al.* Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

D. U.S. Patent 6,205,352, Kitamura et al. and U.S. Patent 5,732,704

Claims 23-32, 34, 35 and 39-57 stand rejected under §103(a). As acknowledged by the preceding rejection over U.S. Patent 6,205,352 and Kitamura *et al.*, these reference fails to describe the elements of previous claim 24, which are now part of claim 1. Thus, this disclosure – use of a carbon particle with a dye – must come from U.S. Patent 5,732,704. However, it does

not disclose this feature. Rather, even examiner acknowledges that U.S. Patent 5,732,704 *only* discloses use of dyes to identify sentinel lymph nodes. Nonetheless, it is argued that “the concomitant use of carbon particles and blue dye would have been obvious because both have been used in the prior art to identify sentinel nodes.” Applicants traverse.

As should be clear, the entire rejection is premised on the obviousness of selecting carbon particles from one reference and a dye from another, and combining them in a single method. This makes no sense whatsoever. Why would one of skill in the art choose to combine these two compositions when the use of one renders the other redundant? This is truly a case of the examiner finding motivation to combine the reference *not* from the references themselves, as required, but only by using applicant’s own specification as a road map. *In re Carroll*, 202 USPQ 571 (CCPA 1979) (“One of the more difficult aspects of resolving questions of non-obviousness is the necessity ‘to guard against slipping into the use of hindsight.’”), citing *Graham v. John Deere Co.*, 148 USPQ 459 (U.S. Sup. Ct. 1965). Applicants submit that it is incumbent upon the examiner to find the suggestion to combine carbon particles and dyes *in the cited art*, and not to simply create such a suggestion out of thin air. *In re Soli*, 137 USPQ 797 (CCPA 1963).

Thus, applicants submit that the examiner has not carried the PTO’s burden of establishing a *prima facie* case of obviousness. Reconsideration and withdrawal of the rejection is, therefore, respectfully requested.

V. **Conclusion**

In light of the foregoing, applicants respectfully submit that all claims are in condition for allowance, and an early notification to the effect is earnestly solicited. Should the examiner have any questions regarding this response, a telephone call to the undersigned is invited.

Respectfully submitted,

Steven L. Highlander
Reg. No. 37,642
Attorney for Applicant
FULBRIGHT & JAWORSKI L.L.P.
600 Congress Avenue, Suite 2400
Austin, Texas 78701
(512) 474-5201

Date: March 11, 2004